

4115-116 DIV 4

40. A therapeutic composition comprising at least one fraction separated from a sample of native hCG or native β -hCG, wherein the native hCG or native β -hCG has not being purified to homogeneity; and wherein the at least one fraction has an approximate molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD as determined by elution from a gel filtration sizing column relative to the elution of a native hCG heterodimer with a molecular weight of 77 kD, and a β -hCG core protein or peptide with a molecular weight of 10 kD, and is active in inhibiting HIV replication.

42. A therapeutic composition produced by a process comprising the following steps:

a) subjecting a sample comprising native hCG or native β -hCG to a size fractionation procedure, wherein the native hCG or native β -hCG has not being purified to homogeneity; and

b) recovering fractions that inhibit HIV replication.

43. The therapeutic composition of claim 42 wherein the recovered fractions contain material having an approximate molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD, wherein the molecular weight is determined by elution from a gel filtration sizing column relative to the elution of a native hCG heterodimer, having a molecular weight of 77 kD, and a β -hCG core protein or peptide, having a molecular weight of 10 kD.

44. The therapeutic composition of claim 42, wherein the sample is early pregnancy urine.

45. A method for producing a therapeutic composition having anti-HIV effects, said method comprising:

a) subjecting a sample comprising native hCG or native β -hCG to a size fractionation procedure, wherein the native hCG or native β -hCG has not being purified to homogeneity; and

b) recovering fractions active to inhibit HIV infection or replication.

46. The method of claim 45 wherein the size fractionation procedure comprises the steps:

a) loading the sample onto a gel filtration sizing column in a first buffer of 30 mM sodium phosphate, pH 8.3;

4115-116 DIV 4

- C² concl'd*
- b) eluting components of the sample from the column with second buffer of 30 mM sodium phosphate, pH 7.0 and 2 M sodium chloride; and
- c) recovering fractions of the sample having been eluted from the column.

Sub D37

48. The method of claim 47 wherein the sample is early pregnancy urine.

49. The method of claim 48 wherein prior to subjecting the urine to a size fractionation procedure, the sample is subjected to the following steps:

- C3*
- a) adjusting the pH of the urine to a pH of approximately 7.2 causing the formation of a precipitate;
- b) removing the precipitate from the urine;
- c) concentrating the urine;
- d) removing salt and lipid from the urine; and
- e) lyophilizing the urine.

C4

68. A method of treating an HIV infection in a human subject in need of such treatment comprising: administering to the subject an effective amount of a therapeutic composition comprising at least one fraction separated from a sample of native hCG or native β -hCG that has not being purified to homogeneity, and wherein the one fraction has an approximate molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD determined by elution from a gel filtration sizing column relative to the elution of a native hCG heterodimer with a molecular weight of 77 kD, and a β -hCG core protein or peptide with a molecular weight of 10 kD and is active in inhibiting HIV infection and replication.

71. A method of reducing replication of HIV in a human subject in need of such treatment comprising:

C5

administering to the subject an effective amount of a composition to treat HIV infection, the composition being produced by a process comprising the following steps:

- a) subjecting a sample comprising native hCG or native β -hCG to a size fractionation procedure, wherein the native hCG or native β -hCG has not being purified to homogeneity; and
- b) recovering fractions that exhibit anti-HIV effects.

4115-116 DIV 4

82. A pharmaceutical composition comprising
- a) a therapeutic composition of claim 40; and
 - b) a pharmaceutically acceptable carrier.

Please add new claims 84-86.

84. A therapeutic composition comprising at least one fraction separated from a sample of native hCG or native β -hCG, wherein the native hCG or native β -hCG has not being purified to homogeneity; wherein the at least one fraction has an approximate molecular weight selected from the group consisting of 40 kD, 15 kD and 3 kD when separated using sizing column chromatography, and wherein the at least one fraction is active in inhibiting HIV infection and replication.

85. A pharmaceutical composition comprising
- a) a therapeutic composition of claim 84; and
 - b) a pharmaceutically acceptable carrier.

86. A therapeutic composition comprising at least one fraction separated from a sample of native hCG or native β -hCG, wherein the native hCG or native β -hCG has not being purified to homogeneity; and wherein the at least one fraction is active in inhibiting HIV infection and replication

Please cancel claims 41, 69-70 and 74.